



November 22, 2021

EKOS Corporation
Jocelyn Kersten
VP, Quality Assurance, Clinical Regulatory Affairs
11911 North Creek Parkway South
Bothell, Washington 98011

Re: K111705

Trade/Device Name: EkoSonic Endovascular System
Regulation Number: 21 CFR 870.5150
Regulation Name: Embolectomy catheter
Regulatory Class: Class II
Product Code: QEY, KRA

Dear Jocelyn Kersten:

The Food and Drug Administration (FDA) is sending this letter to notify you of an administrative change related to your previous substantial equivalence (SE) determination letter dated August 3, 2011. Specifically, FDA is updating this SE Letter as an administrative correction because FDA has created a new product code to better categorize your device technology.

Please note that the 510(k) submission was not re-reviewed. For questions regarding this letter please contact Gregory O'Connell, OHT2: Office of Cardiovascular Devices, (301) 796-6075, Gregory.OConnell@FDA.HHS.gov.

Sincerely,

Gregory W. O'Connell -S
Digitally signed by
Gregory W. O'Connell -S
Date: 2021.11.22
13:39:32 -05'00'

Gregory O'Connell
Assistant Director
DHT2C: Division of Coronary
and Peripheral Intervention Devices
OHT2: Office of Cardiovascular Devices
Office of Product Evaluation and Quality
Center for Devices and Radiological Health



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room -WO66-G609
Silver Spring, MD 20993-0002

EKOS Corporation
c/o Jocelyn Kersten
11911 North Creek Parkway South
Bothell, WA 98011

AUG - 3 2011

Re: K111705

Trade/Device Name: EkoSonic Endovascular System
Regulation Number: 21 CFR 870.1210
Regulation Name: Continuous Flush Catheter
Regulatory Class: Class II (two)
Product Code: KRA
Dated: June 17, 2011
Received: June 17, 2011

Dear Ms. Kersten:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

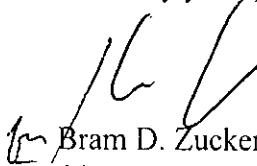
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to <http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm> for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to <http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm> for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address <http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm>.

Sincerely yours,



Bram D. Zuckerman, M.D.

Director
Division of Cardiovascular Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

1.10 Indications for Use Statement

EKOS Corporation
11911 North Creek Parkway South
Bothell, WA 98011

Indications for Use Statement

510(k) Number (if known): K111705

Device Name: EkoSonic Endovascular System

Indications for Use:

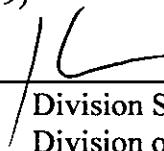
The EkoSonic Endovascular System is intended for the infusion of solutions into the pulmonary arteries.

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use X
(Per 21 CFR 801.109)

OR

Over-The-Counter Use _____


Division Sign-Off
Division of Cardiovascular Devices

510(k) Number K111705

K111705

8.0 510(k) Summary

AUG - 3 2011

Applicant Name: EKOS Corporation

Address: 11911 North Creek Parkway South
Bothell, WA 98011

Contact Person: Jocelyn Kersten
Vice President, Quality Assurance, Regulatory and Clinical Affairs

Telephone: (425) 415-3132

Fax: (425) 415-3102

Device: EkoSonic Endovascular System

Classification: CFR 870.1210 – Continuous Flush Catheter

Panel: Cardiovascular

Product Code: KRA

Intended Use: The EkoSonic Endovascular System is intended for the infusion of solutions into the pulmonary arteries.

Device Description: The EkoSonic Endovascular System is an infusion Device designed to deliver fluids via a multi sidehole catheter. The fluid is dispersed via multiple ultrasound transducers distributed linearly along the length of an MicroSonic Device which is placed into the center lumen of the catheter. This device is intended to deliver physician-specified agents or fluids into the peripheral vasculature.

Predicate Basis: The EkoSonic Endovascular System is substantially equivalent to another legally marketed device. These devices include
1. EKOS EkoSonic Endovascular System (*EKOS Corporation, K081467*)

Performance: EKOS has conducted preclinical bench and animal studies with the EkoSonic Endovascular System. These studies demonstrate that the performance of the EkoSonic Endovascular System meets its design specifications and is safe and effective for its intended use.